REMARKS

The Office Action of March 10, 2008 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Upon entry of this Amendment, claims 1-31 remain in the application. Reconsideration of the claims is respectfully requested.

The Abstract is objected to because, according to the Examiner, it does not allow the public to quickly determine the nature and gist of the technical disclosure nor that which is new. Furthermore, the Examiner points out that the Abstract as filed includes fewer words than is required by 37 C.F.R. § 1.72(b).

In response thereto, Applicant has deleted the Abstract in the specification as filed and has replaced it with a new Abstract submitted herewith. It is submitted that the new Abstract 1) sets forth the nature and gist of the technical disclosure and that which is new, and 2) includes an appropriate number of words, in compliance with 37 C.F.R. § 1.72(b). As such, Applicant submits that the Examiner's objection to the Abstract has been obviated in light of these changes, and withdrawal of the same is respectfully requested.

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because, according to the Examiner, the term "substantially accurately" in claim 1 is a relative term which renders the claim indefinite. The Examiner states that the accuracy of a measurement is a function of many variables that describe a measured value relative to a reference value. The quantitative characterization of accuracy is typically prescribed by the users of the data that include the measurement, *e.g.,* FDA. According to the Examiner, the "relative standard deviation" (as recited in claim 1) is a quantitative characterization of precision (the relative relationship of replicate measurements to one another) rather than accuracy, as a standard.

In response thereto, claim 1 has been amended to recite, "… to substantially accurately dispense a pharmaceutical… *at a predetermined dosage that is substantially reproducible within a variation of reproducibility* of less than about 15%" (emphasis added). Claims 11 and 23 have similarly been amended. Support for such revisions may be found throughout the specification as filed, at least at page 7, line 22 and page 11, lines 16-18.

Applicant submits that the reproducibility of the predetermined dosage (which is a measured value; not repeated measured values) that is within a variation of less than about 15% may sufficiently be described as *accurately* dispensing the pharmaceutical. It is therefore submitted that the 35 U.S.C. § 112, second paragraph, rejection to claim 1 has been overcome in light of this amendment, and withdrawal of the same is respectfully requested.

Claim 2 also stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because, according to the Examiner, the terms "substantially high potent" and "substantially low dosage" are relative. The Examiner asserts that the concepts referred to by these terms are more aptly to be described as "highly concentrated" and "very low volume" or "picoliter volume," respectively. The Examiner further asserts that Applicant's specification as filed tends to support such a characterization, while "potency" and "dosage" imply reference to a specific compound (solute) and use of that compound.

Again, although Applicant does not acquiesce to the Examiner's assertion, in order to expedite prosecution, claim 2 has been amended to recite, "wherein the pharmaceutical includes a *substantially highly concentrated* active pharmaceutical ingredient applied in a substantially low *volume*" (emphasis added). Claims 14 and 24 have similarly been amended. Support for these revisions may be found throughout the specification as filed, at least at page 12, lines 2-12. As such, it is submitted that the 35 U.S.C. § 112, second paragraph, rejection to claim 2 has been overcome, and withdrawal of the same is also respectfully requested.

Further, claim 11 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because, according to the Examiner, there is insufficient antecedent basis for the limitation "fluid jet drops" in the claim. Applicant would like to point out that claim 11 is an independent claim and that the term "fluid jet drops" has not been previously introduced. Thus, it is submitted that the Examiner's rejection is erroneously based, and withdrawal of the same is respectfully requested.

Claims 1, 2, 5, 7-25, and 27-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ellson, et al. (U.S. Patent No. 6,548,308) and *Journal of the Association*

of Laboratory Automation 2003, 8:29-34, referred to hereinafter as Ellson and JALA, respectively. The Examiner asserts that the combination of Ellson and JALA renders obvious independent claims 1, 11, 19, and 23.

Claim 1 has been amended to recite, "A method of using a pharmaceutical dispensing apparatus including a fluid dispenser having a **piezoelectric** fluid ejection device or a **thermal** fluid ejection device…" (emphasis added). Claim 11 has been amended to recite, "A method of precisely reproducing drops of an active pharmaceutical ingredient from a **piezoelectric** fluid ejection device or a **thermal** fluid ejection device of a pharmaceutical dispensing apparatus…" (emphasis added). Additionally, claim 23 has been amended to recite, "A pharmaceutical dispensing apparatus including a fluid dispenser having a **piezoelectric** fluid ejection device or a **thermal** fluid ejection device…" (emphasis added). Support for these new recitations may be found throughout Applicant's specification as filed, at least at page 5, lines 15-17 and page 7, lines 8-18. Claims 6 and 7 have also been amended in order to conform to amended independent claim 1.

In sharp contrast to Applicant's claims 1, 11, and 23, Ellson teaches a method and device for generating droplets of immiscible fluids using **focused acoustic energy**. The use of acoustic energy enables generation of extremely fine droplets, on the order of 1 pL or less, with extraordinarily accurate and repeatable droplet size and velocity. (See column 3, lines 16-21 of Ellson) This is accomplished using an ejector including an acoustic radiation generator for generating acoustic radiation and focusing means for focusing the generated acoustic energy (see column 3, lines 22-25).

Applicant submits that a fluid ejection device employing focused acoustic energy (as taught by Ellson) is clearly **not** the same as a fluid ejection device employing piezoelectric technology or thermal energy, such as with piezoelectric fluid ejection devices and thermal fluid ejection devices, respectively. In fact, Ellson actually *teaches away* from using piezoelectric and thermal fluid ejection devices for accurately dispensing fluid droplets in the picoliter range. Ellson states that use of such fluid ejection devices requires elevated temperatures, which tends to reduce the number of materials that a person can work with because heating these materials may degrade them. Also, Ellson points out that nozzle

clogging tends to be a problem with such devices. (See column 1, line 19 through column 2, line 3).

Independent claims 1, 11 and 23 have also been amended to recite, in some form, "wherein the vehicle is configured to, or exposed to conditions sufficient to substantially prevent instability of the active ingredient during the dispensing of the pharmaceutical." Support for this new recitation may be found throughout Applicant's specification as filed, at least at page 7, lines 8-18. In light of the above discussion of Ellson, it is submitted that the reference clearly does not teach or suggest such a recitation.

It is further submitted that the JALA reference fails to supply the deficiencies of Ellson. Specifically, the JALA reference also teaches the use of focused acoustic energy for accurate fluid ejection of fluid droplets (see, e.g., the Title and page 29, second column). The JALA reference does **not** teach or even suggest using piezoelectric or thermal fluid ejection devices to accomplish the same.

Independent claim 19 has been amended to recite a method of testing piezoelectric and thermal fluid ejection devices. Applicant submits that neither Ellson nor JALA teaches a testing protocol similar to that defined in claim 19. Yet further, neither Ellson nor JALA teaches a testing protocol for piezoelectric and thermal fluid ejection devices. At most, JALA teaches a testing protocol for testing acoustic focused energy devices (see the protocol provided at page 33 of JALA, the first paragraph after the subheading "Precision of Volume Transfer").

For all of the reasons stated above, it is submitted that Applicant's invention as defined in independent claims 1, 11, 19, and 23, and in those claims depending ultimately therefrom, is not anticipated, taught, or rendered obvious by Ellson and the JALA, either alone or in combination, and patentably defines over the art of record.

Claims 3, 4, 6, 7, 15, 26, and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ellson, JALA, and further in view of DrugBank (entry for Digoxin). For the reasons provided above, it is submitted that the combination of Ellson and JALA fails to render obvious: 1) independent claim 1, from which claims 3, 4, 6, and 7 depend; 2) independent claim 11, from which claim 15 depends; and 3) independent claim 23, from

which claims 26 and 31 depend. It is further submitted that the combination of Ellson and JALA also fails to render obvious claims 3, 4, 6, 7, 15, 26, and 31 because of such dependencies. Furthermore, it is submitted that DrugBank does not supply the deficiencies of Ellson and/or JALA. As such, it is further submitted that Applicant's invention as defined in these claims is not anticipated, taught, or rendered obvious by Ellson, JALA and DrugBank, either alone or in combination, and patentably defines over the art of record.

In summary, claims 1-31 remain in the application. It is submitted that, through this Amendment, Applicant's invention as set forth in these claims is now in a condition suitable for allowance. Further and favorable consideration is requested. If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact Applicant's Attorney at the below-listed telephone number.

Respectfully submitted,

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Dated: June 10, 2008
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